K031210

MAY 16 2003

ATTACHMENT C
510(K) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Submitter

Medtronic, Inc.
7000 Central Avenue N.E.
Minneapolis, MN 55432

Contact: Tina Benoit, Regulatory Affairs Specialist
Telephone: (763) 514-4112
Fax: (763) 514-6424
E-Mail: tina.benoit@*medtronic.com*

Date Prepared: April 15, 2003

Name of Device

Device Name:	Medtronic® Model 4951M Myocardial, Unipolar Lead
Device Classification	Cardiovascular Permanent Pacemaker Electrode Class III, 21 CFR, Part 870.3680
Classification Panel	Cardiovascular
Product Code:	DTB

Predicate Devices

The predicate device for the Model 4951M Lead is the currently market released Model 4951M Lead.

Device Description

The Medtronic Model 4951M Myocardial, IS-1 Unipolar Lead is designed for pacing and sensing in either the atrium or ventricle. The lead has application where an implantable atrial, ventricular or dual-chamber pacing system is indicated. Two leads may be used for bipolar pacing.

The lead features a platinized electrode that can be secured to the heart by gently pushing the barbed tip into the epicardium and securing it in myocardial tissue. Suture holes in the polyurethane base pad are provided for greater security. A polyester mesh allows for fibrous ingrowth for additional fixation. The lead also features an MP35N nickel alloy conductor, polyurethane insulation, and an IS-1 Unipolar (UNI) lead connector.

Intended Use

The Medtronic Model 4951M Myocardial, IS-1 Unipolar Lead is designed for pacing and sensing in either the atrium or ventricle. The lead has application where an implantable atrial, ventricular or dual-chamber pacing system is indicated.

Technological Characteristics

The technology used with the Model 4951M Lead has is the same technological characteristics as the predicate device.

Summary of Studies

Based on the bench test results for lead Model 4073 and the MED-4719 material characterization and biocompatibility testing, MED-4719 was qualified by similarity as a strain relief material in Model 4951M.

Packaging

The packaging configuration of the modified Model 4951M Myocardial Unipolar Lead has not changed from the market released configuration of the Model 4951M Myocardial Unipolar Lead (510(k) Document Control Number K894040, cleared 07/14/89, and K913288, cleared 10/17/91).

Sterilization Validation

The Model 4951M Lead is sterilized using a 100% Ethylene Oxide (EtO) sterilization process.

Conclusion

Through data and information presented, numerous similarities support a determination of substantial equivalence and show the device modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device. Market clearance of the Model 4951M Lead is supported through this Special 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2003

Medtronic, Inc.
c/o Ms. Tina Benoit
Regulatory Affairs Specialist
7000 Central Avenue NE
Minneapolis, MN 55432

Re: K031210
Trade Name: Medtronic® Model 4951M Myocardial, Unipolar Lead
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular permanent or temporary pacemaker electrode
Regulatory Class: Class III (three)
Product Code: DTB
Dated: April 16, 2003
Received: April 17, 2003

Dear Ms. Benoit:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):	K031210
Device Name:	Medtronic® Model 4951M Myocardial, Unipolar Lead
Indications For Use:	The Medtronic Model 4951M Myocardial, IS-1 Unipolar Lead is designed for pacing and sensing in either the atrium or ventricle. The lead has application where an implantable atrial, ventricular or dual-chamber pacing system is indicated.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use_____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031210